



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,730	11/18/2003	George F. Fattman	CV0326 NP	4899

26079 7590 09/26/2007
BRISTOL-MYERS SQUIBB COMPANY
100 HEADQUARTERS PARK DRIVE
SKILLMAN, NJ 08558

EXAMINER

CHAPMAN, GINGER T

ART UNIT	PAPER NUMBER
----------	--------------

3761

MAIL DATE	DELIVERY MODE
-----------	---------------

09/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/715,730

Applicant(s)

FATTMAN, GEORGE F.

Examiner

Ginger T. Chapman

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-18 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-18 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

1. By way of Applicant's amendment filed 20 June 2007, claim 2 is canceled; claims 1, 3, 5-18 and 21 are pending in the application.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-3, 6, 12-14 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Cilento et al. (US 4,775,374).

With respect to claims 1 and 21 Cilento discloses a two component ostomy device (10) (column 2, lines 23-24, figures 1 and 3) comprising a body attaching wafer (11) that is adhereable and separable from a pouch component (40) (column 6, lines 23-29, figures 1, 3-4) at a pressure sensitive adhesive interface (31) (column 6, lines 9-13, figure 3) between the two components, each component having a surface on opposite sides of the adhesive interface (fig. 3: 31) and the adhesive interface is coated onto at least one of the surfaces (figs. 3 and 6), said interface (31) including a polysiloxane [note that adhesive layer (31) is made from the same ingredients as adhesive layer (11)] (column 2, lines 48-54, column 4, lines 50-51 and lines 58-67) coats porous backing layer 32 of component C (column 4, lines 50-55, figure 3).

With respect to claim 3 Cilento discloses 35-65% hydrocolloids (column 3, lines 51-56, column 5, lines 9-17).

With respect to claim 6 Cilento discloses 10% plasticizer (column 4, line 67-column 5, line 4 and lines 17-19).

With respect to claims 12-13 Cilento discloses additional plasticizers improve tack (column 2, lines 48-54) and include mineral oil (column 3, line 64-68).

With respect to claim 14 Cilento discloses an antibiotic medicament (column 3, line 67-column 4, line 6).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 5, 7-11, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilento et al. (US 4,775,374) in view of Lin (US 5,580,915).

With respect to claims 5 and 7, Cilento discloses silicone/polysiloxane adhesive 31 as discussed above with respect to claim 1. Cilento does not expressly disclose the listed siloxane adhesives. Lin discloses a polydioganosiloxane pressure sensitive adhesive (column 3, lines 7-10, and lines 64-67) that readily sticks to a solid support such (column 8, lines 5-18) and prevents the migration of the adhesive through the support surface (column 8, lines 18-35). One would be motivated to modify the siloxane adhesive of Cilento with the polydioganosiloxane of Lin for increased adhesive performance and to prevent adhesive migration since the references disclose siloxane pressure sensitive adhesives. Therefore, it would be obvious to one of ordinary

skill in the art at the time the invention was made to modify the adhesive, thus providing a polydioganosiloxane adhesive.

With respect to claims 8-10, Lin further discloses silicate resins (column 4, lines 25-26) that has silanol functionality (column 4, lines 35-57).

With respect to 11, Cilento/Lin disclose the siloxane and resin as discussed above with respect to claims 1 and 8 and thus Cilento/Lin inherently disclose the ratio of resin to siloxane since the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not expressly disclose not render the old composition patentably new to the discoverer. *Atlas Powder Co. v. Ireco Inc.*, 190F.3d i342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). When the reference discloses all the limitations of a claim except a property or function, and the examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § 2112- 2112.02.

With respect to claims 16-17, Cilento/Lin do not expressly disclose the peel strength of the adhesive discussed above. However, peel strength is a result effective variable since it is a result of peel rate, probe speed and type of adhesive used (as supported by Lin column 9, line 48-column 10, line 3). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Cilento/Lin with the claimed peel strength values, since it

Art Unit: 3761

has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch and Slaney*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

With respect to claim 18, Cilento/Lin do not expressly disclose adhesive weight values. However these values are known result effective variables since they are a result of the area to be coated by adhesive. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify Cilento/Lin with the claimed coat values, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch and Slaney*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

5. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cilento et al. (US 4,775,374).

With respect to claim 15, Cilento discloses the plasticizing component as discussed above with respect to claim 12. Cilento does not expressly disclose the percent formulation. However, percent formulation is a well known result effective variable since it is a result of the type of material the adhesive will be used on (i.e., an adhesive on a non-woven film will have a different formulation than an adhesive used on a porous, spongy woven material due to differences in substrate surfaces and the requisite tack for those surfaces). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Cilento with the aforementioned values, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch and Slaney*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980). Moreover, a compound and all its properties are inseparable. *In re Papesch*, 315 F.2d 381,391,137 USPQ 43, 51 (CCPA 1963).

Response to Arguments

Applicant's arguments filed 20 June 2007 have been fully considered but they are not persuasive. Applicant argues the following:

Applicant argues that claim 2 has been canceled and the limitations of claim 2 incorporated into claim 1. This argument is not persuasive because claims 1 and 2 were previously rejected thus the claims as amended do not distinguish over the prior art of record and thus do not overcome the previous rejection.

Applicant argues that Cilento discusses mechanical coupling while the instant claims involve adhesive coupling. This argument is not persuasive because Cilento discloses at column 4, lines 45-50 that coupling by adhesive is a suitable form of coupling. Cilento further discloses at column 2, lines 5-20 that the second adhesive component overlaps the flange of the coupling element and exposed portions of the first adhesive element. Cilento further discloses an embodiment wherein the porous adhesive component is bonded to the top of the first adhesive component, and the coupling element is then affixed to the adhesive component.

Applicant argues that Lin teaches the adhesive can be used with numerous materials but does not explicitly teach using the adhesive on an ostomy device. This argument is not persuasive because the examiner is relying on Lin for the teaching of polydiorganosiloxane as modifying the silicone/polysiloxane of Cilento.

Additionally, In response to applicant's argument that Lin does not explicitly teach using polydiorganosiloxane on an ostomy device, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure

Art Unit: 3761

is capable of performing the intended use, then it meets the claim. In the present case, Cilento/Lin has met the structural requirements of the claimed adhesive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571) 272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ginger Chapman
Examiner, Art Unit 3761
09/17/07



TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

